

REMARKS

Claims 11 and 30 have been amended. Claims 1-10, 13 and 15 have been canceled. Claims 22-29 have been withdrawn. No new matter has been added. Thus, claims 11, 12, 14 and 16-30 remain pending in the present application. In view of the above noted amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claim 30 stands rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Publ. Appln. No. 2004/0143265 to Landry et al. ("Landry").

Amended claim 30 recites a bone screw comprising "a head, *a cannulated shaft extending distally from the head* and having a longitudinal axis, *a proximal section adjoining the head* wherein the proximal section is at least partially threaded, and a distal section polyaxially associated with the proximal section, *the distal section being separated from the head by the proximal section.*"

It is respectfully submitted that Landry does not teach or suggest a bone screw comprising "a head [with] a cannulated shaft extending distally from the head" in combination with "a proximal section adjoining the head" and "a distal section polyaxially associated with the proximal section, *the distal section being separated from the head by the proximal section,*" as recited in claim 30. Rather, Landry is directed to a collar 112 having a bone fastener 108 positioned distally therethrough and being selectively angled as needed, wherein the entire bone fastener 108 is angled relative to the collar 112. (See Landry, ¶ [0125]-[0126]; Fig. 6). That is, no two portions of the bone fastener 108 of Landry are polyaxially movable relative to one another. To overcome this deficiency in Landry, the Examiner has analogized the head 118 of the bone fastener 108 to the "head" of claim 30, a proximal portion of the bone fastener 108 to the "proximal section adjoining the head" of claim 30 and the collar 112 of Landry to the "distal section" of claim 30. (See 3/2/10 Final Office Action, p. 2). It is first respectfully submitted that

the collar 112 is not located distally of the bone fastener 108 and therefore fails to meet the limitations inherently taught by the recitation of a “proximal section” and a “distal section,” wherein one skilled in the art could easily conclude that the proximal section is always located proximally of a “distal section,” especially in an operative configuration. In contrast, the device of Landry is explicitly configured so that the collar 112 is always located proximally of the bone fastener 108. It is respectfully submitted that claim 30 is allowable for at least this reason.

Furthermore, it is respectfully submitted that the purported distal section of Landry, the collar 112, also fails to meet the limitation of “the distal section being separated from the head by the proximal section,” as recited in claim 1. Rather, by the Examiner’s interpretation, the purported distal section, the collar 112, of Landry is in direct contact with the head 118 of the bone fastener. (See Landry, Fig. 2). Furthermore, the device of Landry is incapable of being modified to overcome this deficiency since the head 118 and inner surface of the collar 112 are specifically configured to contact one another to permit angulation of the bone fastener 108 relative to the collar. (*Id.* at ¶ [0125], [0133]; Figs. 2-6). It is therefore evident that nothing in Landry is capable of meeting the limitation of a “distal section being separated from the head by the proximal section,” as recited in claim 30 and furthermore, that the device of Landry is incapable of being modified to overcome this deficiency as doing so would prevent rotation of the bone fastener 108 relative to the collar 112.

It is therefore respectfully submitted that Landry fails to teach or suggest the limitation of “a *distal section polyaxially associated with the proximal section, the distal section being separated from the head by the proximal section,*” as recited in claim 30 and that claim 30 is therefore in condition for allowance.

Claims 11-12, 14, 16-19 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,050,997 to Mullane in view of Landry.

Amended claim 11 recites a bone screw comprising “a head having a first outer diameter,

and a cannulated shaft extending distally from the head and having a longitudinal axis, the cannulated shaft further comprising a proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter, an outer wall of the proximal section being at least partially threaded, and a distal section extending distally from the proximal section and being attached to the proximal section by way of a ball-and-socket joint.”

It is respectfully submitted that Mullane and Landry fail to teach or suggest “a head having a first outer diameter” in combination with “a cannulated shaft extending distally from the head... the cannulated shaft further comprising a proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter...and a distal section extending distally from the proximal section and being attached to the proximal section by way of a ball-and-socket joint,” as recited in claim 11. Rather, Mullane is directed to a support collar 18 having a first outer diameter and a shaft of a pedicle screw 20' extending distally therefrom, the shaft being entirely threaded and having a uniform outer diameter, the pedicle screw 20, 20' being pivotable relative to a ball end 40 of a toggle bolt 22. (See Mullane, col. 6, ll. 36-59; col. 10, ll. 29-38; Figs. 1, 4, 14). There is no portion of the device of Mullane extending distally from the support collar 18 capable of meeting the limitation of “a proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter” in combination with “a distal section extending distally from the proximal section and being attached to the proximal section by way of a ball-and-socket joint,” as recited in claim 11. Rather, the entire portion of pedicle screw 20, 20' shaft extending distally from the support collar 18 comprises a uniform outer diameter. Still further, there is no ball-and-socket joint positioned distally of the support collar 18 at all. Rather, the spherical ball 40 of Mullane is embedded within the support collar 18 proximally of the shaft of the pedicle screw 20, 20'. (*Id.*). Furthermore, since Mullane teaches that it is the toggle bolt 20/locking bolt 122 of the anchoring assembly 12 which is pivotable relative to the pedicle screw 20/20', respectively, there is no motivation to add any ball-and-socket mechanism distally of the support collar 18. (*Id.* at col. 1, ll. 49-62; col. 7, ll. 3-21). Such a modification would further prove detrimental to the device of Mullane since any ball-and-socket joint located distally of the support collar 18 would rotate freely and prevent a user from

controlling an angle of insertion thereof into a target bone as well as prevent a secure anchoring of the anchoring assembly 12 to the spine. It is therefore respectfully submitted that Mullane fails to teach or suggest and is further incapable of being modified to overcome the limitations of “a proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter” in combination with “a distal section extending distally from the proximal section and being attached to the proximal section by way of a ball-and-socket joint,” as recited in claim 11.

Landry fails to cure these deficiencies in Mullane. Specifically, as noted earlier, Landry teaches a collar 112 having a bone fastener 108 extending distally therefrom and selectively angled as needed. (See Landry, ¶ [0125]-[0126]; Fig. 6). Landry also fails to teach or suggest a device having a head at a proximal end and proximal and distal sections extending distally therefrom, respectively, wherein the distal section is connected to the proximal section via a ball-and-socket joint.

It is therefore respectfully submitted that Mullane and Landry, taken alone or in combination, fail to teach or suggest “a proximal section adjoining the head and having a second outer diameter smaller than the first outer diameter” in combination with “a distal section extending distally from the proximal section and being attached to the proximal section by way of a ball-and-socket joint,” as recited in claim 11 and that claim 11 is therefore in condition for allowance. Because claims 12, 14, 16-19 and 21 depend from and therefore include all of the limitations of claim 11, it is respectfully submitted that these claims are also allowable.

Claim 20 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Mullane in view of Landry in further view of U.S. Publ. Appln. No. 2004/0236330 to Purcell et al. (“Purcell”).

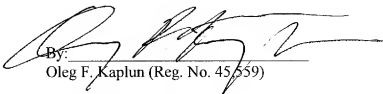
Claim 20 depend from and therefore includes all of the limitations of independent claim 11. As noted above, Mullane and Landry fail to teach or suggest the limitations of claim 11.

Purcell fails to cure these deficiencies. It is therefore respectfully submitted that Mullane, Landry and Purcell, taken alone or in any combination, fail to teach or suggest the limitations of claim 11 and that claim 11 is therefore in condition for allowance. Claim 20 is therefore also allowable as being dependent on an allowable base claim.

In view of the remarks submitted above, the Applicants respectfully submit that the present case is in condition for allowance. All issues raised by the Examiner have been addressed, and a favorable action on the merits is thus earnestly requested.

Respectfully submitted,

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